Quarterly Progress Report

N01-NS-1-2333

Restoration of Hand and Arm Function by Functional Neuromuscular Stimulation

Period covered: July 1, 2003 to September 30, 2003

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Contract abstract

The overall goal of this contract is to provide virtually all individuals with a cervical level spinal cord injury, regardless of injury level and extent, with the opportunity to gain additional useful function through the use of FNS and complementary surgical techniques. Specifically, we will expand our applications to include individuals with high tetraplegia (C1-C4), low tetraplegia (C7), and incomplete injuries. We will also extend and enhance the performance provided to the existing C5-C6 group by using improved electrode technology for some muscles and by combining several upper extremity functions into a single neuroprosthesis. The new technologies that we will develop and implement in this proposal are: the use of nerve cuffs for complete activation in high tetraplegia, the use of current steering in nerve cuffs, imaging-based assessment of maximum muscle forces, denervation, and volume activated by electrodes, multiple degree-of-freedom control, the use of dual implants, new neurotization surgeries for the reversal of denervation, new muscle transfer surgeries for high tetraplegia, and an improved forward dynamic model of the shoulder and elbow. During this contract period, all proposed neuroprostheses will come to fruition as clinically deployed and fully evaluated demonstrations.

Overall status

Because this contract has passed its halfway point in terms of duration, this section has been included to summarize its overall status. This summary elaborates on the presentation recently given at the 2003 Neural Prosthesis Program Workshop.

Technology

Nerve cuff electrodes. A substantial effort has been invested in bringing nerve cuff electrodes into use in the human upper extremity because they basically guarantee complete activation of potentially weak muscles and because they have the long range potential to allow selective activation of several muscles from a single cuff. Nerve cuff electrodes are particularly appropriate for the proximal joints of the upper extremity because most of the nerves serve a single muscle or just a few synergistic muscles, because these muscles have highly branched intramuscular innervation patterns that are not well suited for muscle-based electrodes, and because these muscles have large motions that tend to wrap along bony surfaces.

During this contract period, we have set up a manufacturing capability that will allow the fabrication of electrodes to specific sizes and electrode configuration (i.e., single or multiple contacts). We have developed a surgical tool to aid the surgeons in installing the cuff electrodes quickly and with minimum trauma to the nerve. We have performed a large series of cadaver dissections that demonstrated that all of the nerves of interest are large enough in diameter and have sufficient branch-free lengths to accept the cuffs. We have obtained an IDE from the FDA that allows these cuffs to be permanently installed in the upper extremities of human subjects. We have performed a set of intraoperative tests during nerve repair surgeries to demonstrate the ability to install the cuff electrodes on nerves of interest and the ability to selectively activate a single muscle from a multi-fascicle nerve trunk.

We are now poised to implant permanent cuff electrodes in human upper extremity nerves as part of a neuroprosthesis for high tetraplegia.

Twelve channel implanted stimulator with EMG inputs. This stimulator is central to all of the implanted systems to be implemented during this contract. The number of stimulation channels has been extended from 8 to 12 (relative to the "Freehand" system) and two bipolar EMG

channels accept inputs from fully implanted EMG electrodes. A human subject was recently implanted with this 12 channel implanted stimulator and control of hand opening and hand closing was demonstrated using EMG signals from the brachioradialis and trapezius, respectively.

We have demonstrated an advanced 12-channel implanted stimulator with hand grasp control via two EMG input channels as a permanent neuroprosthesis in a human subject. It will be used in all of the implanted neuroprostheses implemented in this contract.

High performance external controller. During the past year we demonstrated a new external control unit that uses a single board computer to provide the computational capacity needed to implement the advanced control methods proposed for the various projects in the contract. As a demonstration, the hand grasp control method was successfully implemented using a block diagram-based package within the Matlab environment. This combination of substantial processing power and intuitive programming interface will significantly accelerate the pace of controller algorithm development and significantly increase the effectiveness of these control algorithms.

We have demonstrated an advanced external control unit that has substantial computational power and is relatively simple to program. It will be used in the high tetraplegia and C5-C6 SCI neuroprostheses being developed in this contract.

External sensor telemetry system. We have prototyped a telemetry system for external sensors and switches associated with the various neuroprostheses being developed in this contract. Most neuroprosthesis users push a wheelchair-mounted switch to turn on the system. At a minimum, this small, battery operated telemetry system will replace the cable associated with this switch. The real benefits of this telemetry system, however, will be in the use of more advanced external sensors such as 3D accelerometers, 3D orientation sensors, and facial EMG or EEG signals. The signals from these sensors will be used both for command (i.e., the user specifying the desired action) and control (i.e., the neuroprosthesis driving the joint or joints in the manner commanded by the user).

We have prototyped an external telemetry system that will greatly simplify the use of external sensors during neuroprosthesis development by eliminating most or all of the associated cables.

New tools for developing or augmenting neuroprostheses

Neurotization surgical procedures for SCI. Denervation occurs for all levels of SCI due to the damage of motoneuron pools near the site of injury. Denervation is of particular concern for the implementation of neuroprostheses because denervated muscle cannot be safely induced to contract via electrical stimulation. Denervation is particularly a concern for some individuals with C4 SCI because the deltoid and biceps muscles, both critical for functional use of the arm, tend to be partially or completely denervated.

We have begun the evaluation of neurotization surgical procedures that graft viable nerves into nerves that would otherwise denervate, potentially making the muscles served by these nerves available to a neuroprosthesis. This approach is commonly taken following brachial plexus injury to rescue the deltoid, rotator cuff muscles, and biceps to save some function, but has not been widely adopted following high cervical SCI because of uncertainty regarding the

degree of natural recovery. Surgeons in our group have recently begun performing these clinical procedures in individuals who have reached a chronic steady state (two years post-injury or greater). The results of these procedures are expected to take a long time to develop and are not expected to be optimal because (1) the ability of a muscle to accept new innervation decreases with time and (2) lack of activity and motion during this period leads to contractures and other irreversible changes. As part of this contract, we are collecting a variety of physiological data from SCI subjects beginning immediately after injury and extending out to the chronic state. We expect to use these data to develop an early predictor of denervation so that these surgeries can be performed much earlier and have a much higher success rate without compromising potential natural recovery.

We have begun to perform neurotization surgeries in chronic SCI subjects with high tetraplegia in an attempt to prevent or reverse denervation of key muscles needed for the implementation of a neuroprosthesis. Work continues in parallel to develop an approach that would allow the accurate prediction of denervation soon after the SCI so that the neurotizations could be performed earlier and with a higher success rate.

Musculoskeletal modeling and simulation. Musculoskeletal modeling is the process by which the mechanical properties of a limb or limbs are described mathematically. This description includes the mass and inertial properties of the limb segments, the geometry of the limb, and the properties of the muscles that power the limb. Simulations use the model to predict the outputs for a given set of inputs (forward simulation) or to determine the set of inputs needed to achieve a desired output (inverse simulation). Simulations performed with a musculoskeletal model are relevant for neuroprosthesis development because they allow many different situations to be examined *before* a neuroprosthesis is actually implemented. That is, the model replaces an actual human subject for a significant portion of the development cycle, allowing the use of powerful mathematical tools to optimize performance and reducing the burden on human subjects.

We have recently developed a forward dynamic model of the human shoulder and arm that is essential for the continued development of a feedback controller for arm position in individuals with high tetraplegia. We are currently in the process of validating this model experimentally, after which the controller development will begin in earnest.

We have developed a powerful new tool for musculoskeletal modeling and simulation that will accelerate the development of the feedback controller for arm position in the high tetraplegia neuroprosthesis. In the longer term, this basic approach could be applied to many other potential user groups and for many other control strategies.

Robotic simulator for command and control interface development. One of the requirements for a neuroprosthesis for high tetraplegia is that the user must be able to command the location of their hand in space in a reasonably effective and natural manner. There are a large number of potential approaches for providing this command interface, including head and eye movements, facial EMG signals, voice commands, EEG signals, and even cortical recordings. We are currently in the process of developing both quantitative and subjective assessment tools for evaluating these different command sources and combinations of these sources. To facilitate these evaluations, we have recently developed a robotic device that is human sized and has joint motions comparable to the human arm. Human subjects control this robotic arm as if it was their own paralyzed arm, emulating the situation for individuals with high tetraplegia and allowing the rapid evaluation of a number of different command schemes. Note that this approach is similar to

the approach used in the various cortical control projects. However, the cognitive ability of human subjects is expected to lead to substantially improved results.

We have developed a robotic arm simulator that will allow the rapid development of a command interface for the neuroprosthesis for high tetraplegia. Any command signal of interest, or combinations of several signals, can be easily evaluated. We are currently focusing on readily obtainable signals such as head orientation, eye movements, and facial EMGs. Continued developments in brain surface EEG (i.e., ECoG) and cortical signals can be evaluated as they become available.

EMG-based control methods

Several of the neuroprostheses that are being developed during this contract will use EMG recordings from different muscles as part of the command and control interface. EMG signals provide easy access to the retained motor output of the nervous system, with several significant advantages. EMG signals require simple sensors (i.e., bipolar electrodes and an amplifier) that are relatively easy to build and install in human subjects. EMG signals can be used to directly control a particular action in a proportional manner or can be used as on-off switch signals. EMG signals can be used as control signals even if the amplitude of the accompanying contraction is too small to produce significant motion. Neural adaptation can be reflected in the EMG signals recorded, providing the potential for the user to adjust to the neuroprosthesis control algorithm and thus optimize performance.

EMG-based control schemes have already been evaluated to control different movements in different user groups. As noted above, we have recently implanted a neuroprosthesis with a 12-channel stimulator and 2 implanted EMG inputs into an individual with a C5 SCI. He controls hand opening and hand closing using EMG activity in the brachioradialis and trapezius muscles, respectively. This mimics and extends earlier control methods that monitored actual shoulder and wrist movements to control hand function.

We have also recently demonstrated the synergistic control of hand function in C7 users via wrist flexor EMG (hand opening) and wrist extension EMG (hand closing). This method mimics and reinforces the natural tenodesis mechanics that link wrist motion to hand opening and closing, and it thus is natural and effective.

We have also begun the evaluation of EMG recordings as control signals at joints with mixed voluntary control and paralysis. The basic idea in this approach is to record EMG signals from muscles with retained voluntary function and use these signals to predict the stimulation levels needed for paralyzed muscles at the same joint or adjacent joints. In essence, the existing voluntary control is used to infer the movement being attempted by the user and the correct stimulation levels for paralyzed muscles are computed and applied so that the user is automatically and naturally assisted in their motions. A good analogy for this approach is the power steering mechanism used in automobiles, which senses a desired steering motion and reduces the effort needed to make that motion. This approach is currently being evaluated to control the elbow joint in C5-C6 SCI, which exhibits a mixture of voluntary control (elbow flexors) and paralysis (elbow extensors). The elbow flexors can be used to turn off stimulation to the elbow extensors in a reciprocal manner, but it is more difficult to determine when to turn on the stimulation to the elbow extensors. This has been resolved through the use of simulations with a musculoskeletal model. The model has been used to estimate the muscle activation levels needed in both voluntary and paralyzed muscles to perform a wide range of motions. An artificial neural network was then trained to predict the needed activation of paralyzed muscles

(i.e., stimulation values) from the voluntary muscle activations (i.e., EMG recordings). After normalization of both EMG and stimulation values relative to maximum for that particular subject, this approach was found to produce appropriate control. Continuing work will demonstrate this approach in several subjects performing a wide range of functional activities. This same approach will be extended to control several motions at the shoulder, which presents a similar mixture of volitional and paralyzed musculature.

EMG-based neuroprosthesis control has a number of significant advantages that we are exploiting for control of different joints in users with different injury levels. Several new control schemes have already been demonstrated in neuroprosthesis users during this contract and advanced schemes are under active development. The new 12-channel implantable stimulator with two EMG input channels offers a convenient platform for practical implementation of these control algorithms.

Summary

This contract has two general goals: (1) extend the benefits of neuroprostheses to individuals with both high and low tetraplegia and (2) increase the functionality of neuroprostheses for individuals with mid-level (C5-C6) tetraplegia. A variety of different methods and approaches are being used, but all are focused on attaining these two goals. We have made substantial progress on all of the sub-projects of this contract and are currently on schedule to implement the proposed implanted neuroprostheses in individuals at all 3 levels (low, middle, and high tetraplegia). The implementation of actual implanted neuroprostheses in this project will allow us to demonstrate the feasibility of the approaches taken while also developing the specifications for neuroprostheses that can be more broadly deployed in an effective manner to each of the user groups.

We are also developing a number of basic tools that can be applied in the future to additional user groups. For example, the use of EMG-based control in individuals with complete SCI in the current contract can be easily and naturally extended to individuals with incomplete injury in the future. Other groups that will be targeted in the future include stroke (via EMG-based control) and brachial plexus injury (similar in many ways to high tetraplegia). The technical advances being made during this contract period lead naturally into several additional areas. For example, we could exploit the multi-contact cuff electrodes being developed during this contract to control several muscles via a single cuff electrode, and expand the use of cuff electrode to additional joints. The advantages here would be lower power consumption, location of electrodes away from high stress areas, and perhaps lower impact surgical procedures. We are also interested in continuing the spirit of the neurotization work by developing a variety of methods for preventing denervation following SCI, perhaps via implantation of motoneurons or precursor cells in the periphery. The command and control challenge for individuals with high tetraplegia can potentially be addressed through the use of brain-based recordings (ECoG or cortical neuron recordings) that are becoming closer to human implementation. The availability of more powerful computational units and more stimulation channels opens up the possibility to apply principals of adaptive control to the various neuroprostheses, which could have the ability to automatically adapt to an individual user and compensate for changes in the system (e.g., fatigue). Finally, the use of simulations based on musculoskeletal modeling has a huge potential for accelerating the development of neuroprosthesis control systems and for the evaluation of surgical procedures (e.g., muscle tendon transfers) that complement the stimulation-based restoration.

Summary of activities during this reporting period

The following activities are described in this report:

- *Measurement of human upper extremity nerve diameters and branch-free lengths*
- *Intra-operative testing of nerve cuff electrodes and implant tools*
- *Wireless data acquisition module for use with a neuroprosthesis.*

Measurement of human upper extremity nerve diameters and branch-free lengths.

Contract sections:
E.1.a.i Achieving Complete and Selective Activation Via Nerve Cuff Electrodes
E.2.a.i Selective Activation of Elbow and Shoulder Muscles by Nerve Cuff Electrodes

Introduction

The ability to activate selectively peripheral nerve trunk fascicles using nerve cuff electrodes is well established. In the effort to combine several upper extremity functions into a single neuroprosthesis we will use this technology for specific muscle activations. External and internal topography studies of the upper extremity nerves are necessary to identify candidate implant sites. The external study has been reported previously and included measurements of the diameters and branch free lengths of the target nerves in six complete brachial plexus dissections. The results of this study indicated acceptable diameters and branch free lengths at the targeted cuff sites.

The goal of the internal study is to obtain accurate fascicle topographies at the targeted areas. To increase the amount of information obtained from the internal studies, the use of a set of lipophilic dyes that retrogradely diffuse in fixed nerve tissue is being pursued. A method using applied dc electric fields to enhance the diffusion of these dyes has been shown to significantly increase the diffusion velocities of the dyes. In this quarter we have tested this technique on other, differently colored, lipophilic dyes. This vision is to dye multiple distal nerve branches, each with a different dye, to create a proximal map with "color coded" axons.

Methods

Each of four lipophilic dyes (DiI, DiO, Dir, DiA) was dissolved in ethanol at a ratio of 1 mg/ml, and applied via a micropipette to a triangular cross-section made 1 cm from the end of a 6 cm nerve sample of either human median or ulnar nerves. Platinum plate electrodes were then positioned at either end of the nerve sample with the electrode closer to the initial DiI loading site serving as the anode (Figure 1). A dc electric field of 30 V/cm was applied across the nervous tissue for durations of 24 hours. Following this tracing period, the nerve samples were embedded in polyacrylamide and cross-sectioned to reveal the extent of dye diffusion.

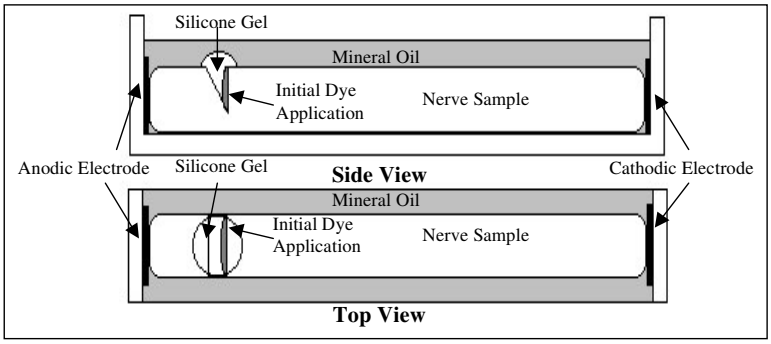

Figure 1. Schematic of Experimental Set-up

Results

The velocity enhancements that were seen with DiI were repeatable with the analogous dyes. Figure 2 shows a comparison of the four dyes for the tracing distances obtained with a field strength of 30 V/cm being applied for 24 hours. All of the dyes were shown to exhibit enhanced diffusion velocities when subjected to the electric field. DiA was seen to diffuse 12.25 mm from the initial loading site, DiR 15.5 mm, and DiO 13.5 mm. These results all represented significant increases in dye diffusion velocities.

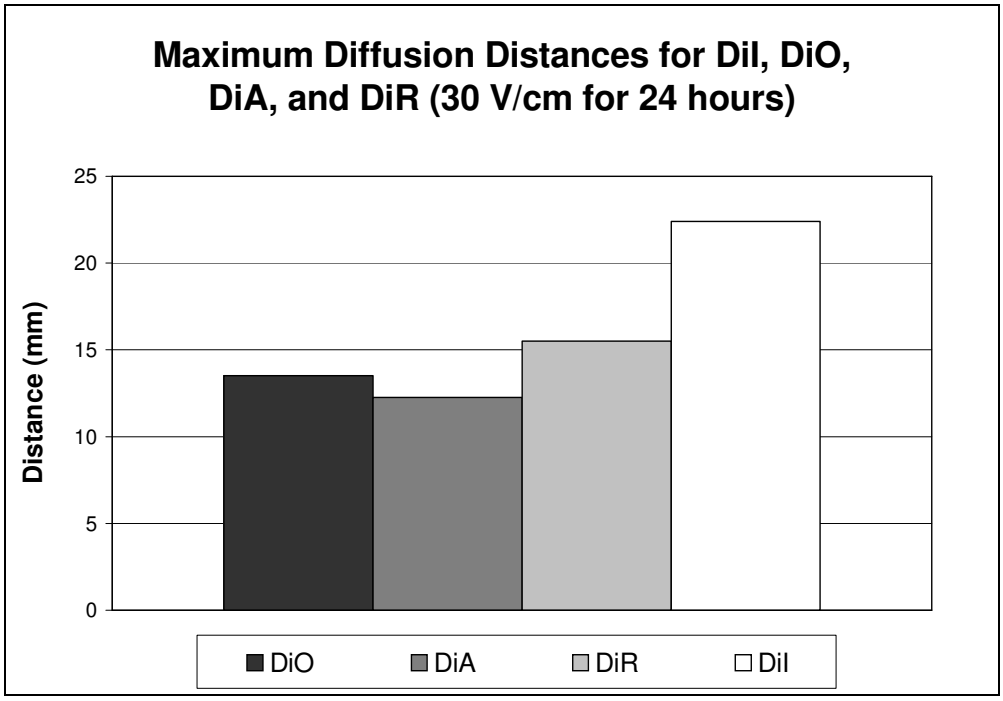

Figure 2. Comparison of tracing distances obtained with four different lipophilic dyes obtained in human peripheral nerve exposed to a 30V/cm field applied for 24 hours.

Intraoperative Testing of Nerve Cuff Electrodes and Implant Tools

Contract sections:
E.1.a.i.4.3 Nerve Cuff Electrode fabrication and implantation

Introduction

The purpose of this section of the contract is to fabricate and develop the surgical methods to implement nerve cuff electrodes in a Functional Electrical Stimulation system. Nerve cuff electrodes are required to extend the benefits of neuroprostheses to individuals with a high cervical injury (C1-C4). These individuals present additional technical and medical problems compared to the C5/C6 patients with which we have extensive experience. First, there are more paralyzed muscles than in lower level injuries, requiring many more electrodes. Second, a C4 level injury causes important muscles to be partially denervated. Since the denervated portions of the muscles cannot be stimulated, the number of motor units and potential force output of these muscles is reduced. Third, many of the muscles that need to be stimulated are broad and undergo large motions over bony prominences. It is difficult to use standard muscle-based electrodes in these muscles.

Nerve cuff electrodes have the potential to solve many of these problems. Cuff electrodes have multiple contacts that wrap around the nerve and can be controlled individually. Stimulating a single contact can activate the portion of the nerve closest to that contact and selectively recruit a single muscle or synergistic muscle group. With multiple contacts, it is possible to control multiple muscles or actions with a single electrode. This reduces the total number of electrodes to be implanted, which shortens the length of the surgical procedure and decreases the number of implanted lead cables.

Nerve cuff electrodes stimulate more efficiently than muscle-based electrodes. In animal models, nerve cuff electrodes require only $1/10^{th}$ to $1/100^{th}$ of the charge required by muscle-based electrodes. In denervated muscle, full activation of all viable fibers is essential for obtaining sufficient force for useful function. Muscle electrodes only activate the motor end-plates adjacent to the electrode. This makes full recruitment of a muscle from a single electrode difficult, especially in the broad muscles of the shoulder. Cuff electrodes are placed on a common nerve trunk proximal to the muscle. Consequently, cuff electrodes can fully activate all remaining innervated muscle fibers, thereby achieving the maximum possible muscle output. Similarly, cuff electrodes can fully activate the broad shoulder muscles with a single electrode.

The CWRU self-sizing spiral nerve cuff electrodes [Naples, Mortimer, et al. 1988] is an attractive electrode for this project. These electrodes are self-sizing coils (Figure 3) with four contacts evenly spaced around the nerve. The natural coiling of these electrodes results in an intimate fit between the nerve and the contacts while still allowing the nerve to swell. The cuff electrodes are approved for investigational use (IDE #G950116). The final steps prior to clinical implementation of the nerve cuff electrode include development of a tool to facilitate cuff implantation and feasibility testing of both the cuff electrode and the tool. Several prototype tools have been developed. Intraoperative testing of both the cuff electrode and the installation tool during upper extremity nerve repair surgeries is in progress. These studies are the final preparation for the implantation of four nerve cuff electrodes with percutaneous leads in an individual with high tetraplegia.

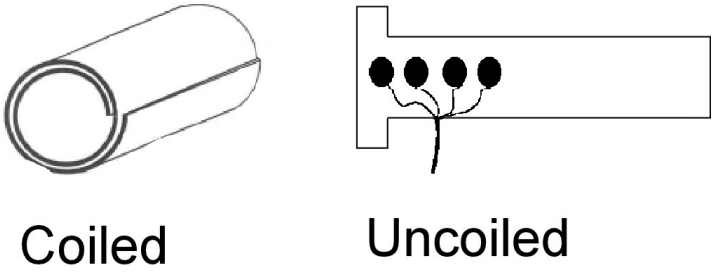

Figure 3: Left – Spiral electrode coiled, resulting in two full wraps. Right – Electrode uncoiled to show contacts.

The objective of work this quarter was to finalize the implantation tool design, test the prototype intraoperatively, and explore the selectivity and stimulation parameters of the nerve cuff electrodes on human upper extremity nerves.

Methods

Subjects were recruited from patients scheduled to undergo upper extremity nerve repair surgery. During these procedures, surgeons tested the viability of potentially injured nerves by measuring somatosensory evoked potentials (SSEP) and electromyograms (EMG). Typically, stimulation would have been delivered through a two-ball hook electrode held on the nerve. For this study the "hands free" spiral nerve cuff electrode was used in place of the ball electrode. Evoked potentials were recorded using needle or corkscrew electrodes placed over the cervical spinal cord, Erbs point, the brainstem, the cortex and within up to four target muscles. Data was collected using a commercially available SSEP system (Epoch 2000, Axon Systems, Hauppauge NY).

The nerve cuff electrode was placed around each nerve using the prototype implant tool. The ease of implantation and surgeon feedback on the design were recorded

The multiple contacts on the cuff electrode allowed the surgeon to stimulate in several places around the nerve and evaluate the nerve's function. The electrode was placed in different orientations on larger nerves to ensure stimulation around the entire nerve. Stimulating through individual contacts was used to demonstrate selectivity. The stimulation parameters were varied at each contact and approximate threshold values were recorded. These threshold values were obtained by turning up the stimulation until a response was seen. This response was recorded and the surgeon advanced to the next contact.

Time constraints of intraoperative testing did not allow for a complete characterization of the selectivity of the cuff electrodes. Therefore, only a few combinations were tested. The pulse amplitude was set to 0.5 mA and the pulse duration was adjusted, starting from 100 μsec until the first response was observed. If no response was seen at 500 μsec, the pulse amplitude was increased to 1.0 mA and the pulse duration again adjusted between 100 and 500 μsec.

Results

Four subjects have participated in this study. Rough threshold data and tool usage comments are recorded in Table 1.

Table 1: Summary of intraoperative testing data.

Subj #	Injury/Condition	Time Post Injury	Threshold***		Stim Pos	Tool Ver	Tool Usage Comments
			Nerve	Value			
1	Nerve avulsion and torn brachial plexus trunks	3 weeks	Phrenic	↓ - 50 μs, 1.7 mA	WC	1	▪ Put Bend in tool-to slide under nerve ▪ Make tool narrower ▪ Add tabs to cuff
				↑- 100 μs, 1.7mA	WC		
			Spinal Acc.	↑- 500 μs, 0.3 mA	WC		
				↑- 100 μs, 1.0 mA	WC		
				↑ - 50 μs, 1.7 mA	WC		
2	Partial amputation at elbow	3.5 weeks	Median	↓ - 75 μs, 1.0 mA	WC	2	▪ Need to lift nerve ▪ Devise way to wrap cuff around nerve
				↑- 100 μs, 1.0 mA	WC		
			Ulnar	↑- 100 μs, 1.0 mA	WC		
3	C4 SCI – nerve transfer	2 years	Upper Trunk	↑- 190 μs, 1.1 mA	2d	2	▪ The tool was mis-aligned due to problems during sterilization and could not grip the cuff adequately.
				↑- 200 μs, 1.1 mA	2e		
				↑- 200 μs, 1.0 mA	3a		
			Ulnar	↓- 125 μs, 1.0 mA	2a		
				↑- 300 μs, 0.5 mA	2a		
				↑- 250 μs, 0.5 mA	2b		
				↑- 275 μs, 0.5 mA	2c		
				↑- 300 μs, 0.5 mA	2d		
				↑- 500 μs, 0.5 mA	3d		
4	Nerve decompression	6 months	N/A – Due to technical problem, unable to stimulate with cuff			3	▪ Easiest version to use. ▪ Very close to final design. ▪ Move hook closer to tips ▪ Improve loading

Legend: "↓" - Subthreshold value; "↑" - Suprathreshold value; "WC" – whole cuff; "Stim Pos" contains a number that refers to the cuff rotation around the nerve and a letter that refers to the contact on the cuff. "Tool Ver" refers to the prototype version discussed in the following section.

***Threshold values are the lowest recorded value that resulted in a response at the stimulation position indicated.

***Tool Evolution*:**

The first version of the tool is described in the previous quarterly report (QPR9_N01-NS-1-2333). The second and third generation implant tools were developed and tested this quarter. The double handed second generation tool (Figure 4) was difficult to manipulate. Wrapping the cuff around the nerve was awkward.

Figure 4. Second generation tool. Two normally closed slightly bent forceps were attached together at the base of the handles.

The third generation tool (Figure 5) allowed the surgeon to hold the cuff securely with one hand. The single handle made the tool easier to manipulate, and the hooks allowed the nerve to be lifted from the surrounding tissue. This provided adequate space for the cuff to be wrapped around the nerve.

Figure 5. Cuff held in third generation tool. Cuff unrolled using slightly bent forceps.

Overall, the surgeon was pleased with the new design. He suggested that the hooks be moved closer to the tips and shortened slightly. He also preferred having the tips open independently for easier loading. With the tool, the surgeon was able to implant the cuff in less than a minute and required only an additional standard strongly bent forceps.

Stimulation:

Two nerves of a subject with a C4 level spinal cord injury were stimulated: the upper trunk of the brachial plexus and the ulnar nerve. The upper trunk of the brachial plexus of a subject was stimulated at approximately 9 different points around the trunk. EMG signals were recorded from the biceps, pectoralis major, deltoid and supraspinatus. Stimulation parameters ranged from 1 mA, 200 μsec (which selectively activated the biceps (Figure 6)), to 2.5 mA, 500 μsec (which activated the biceps, pectoralis major and deltoid). Supraspinatus stimulation was not observed for any of the tested stimulation parameters.

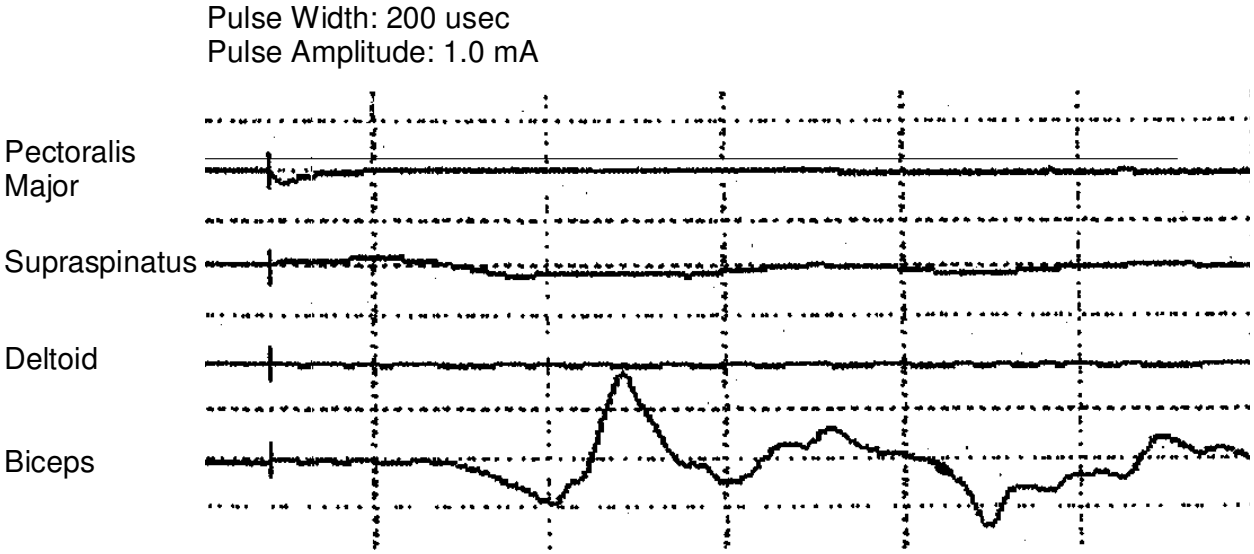

Figure 6. Selective activation of biceps at 200usec and 1.0mA

The ulnar nerve was also stimulated at approximately 9 different circumferential points. EMG signals were recorded from the flexor carpi ulnaris (FCU), flexor digitorum profundus (FDP) and first dorsal interosseous (FDI). Stimulation parameters ranged from 0.5 mA, 500 μsec (which selectively activated the FDI), to 0.9 mA, 125 μsec (which activated all three muscles at several different contacts). Selective activation of the flexor carpi ulnaris (FCU) was also achieved (Figure 7). With stimulation on position 2b only the FCU was activated with parameters of 0.5 mA, 250 μsec. Switching to position 3d, the FDI only was activated with parameters of 0.5 mA, 500 μsec. Time did not allow for further detailed testing to selectively activate the flexor digitorum profundus (FDP).

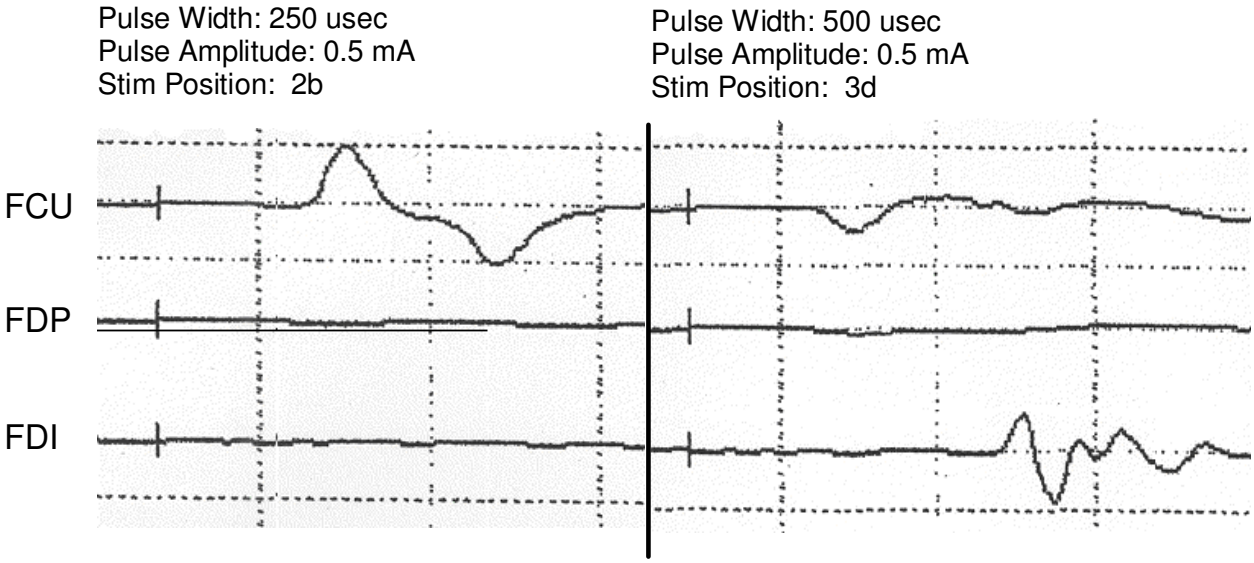

Figure 7. Selectivity demonstrated on ulnar nerve. EMG signals recorded from flexor carpi ulnaris (FCU), flexor digitorum profundus (FDP) and first dorsal interosseous (FDI). Stimulating at different positions around the nerve resulted in selective activation of FCU (stim position 2b) and FDI (stim position 3d).

Discussion

Tool:

While installation time was short (typically less than 1 minute), a mechanism to facilitate wrapping the cuff around the nerve is desired to eliminate the need for assistance. The problem is that the surgeon needs to manipulate the pliant, self-curling spiral behind the nerve. A "shuttle" is being developed to assist the surgeon in wrapping the cuff behind the nerve (Figure 8). The shuttle will attach to the end of the cuff furthest away from the leads. The preliminary concept has the shuttle forming a blunt hook, slightly larger than the estimated nerve diameter. The surgeon will slip the shuttle under the nerve and it will remain there until the surgeon grasps it from the other side. Once the cuff electrode is installed, the shuttle can be trimmed off the end of the cuff.

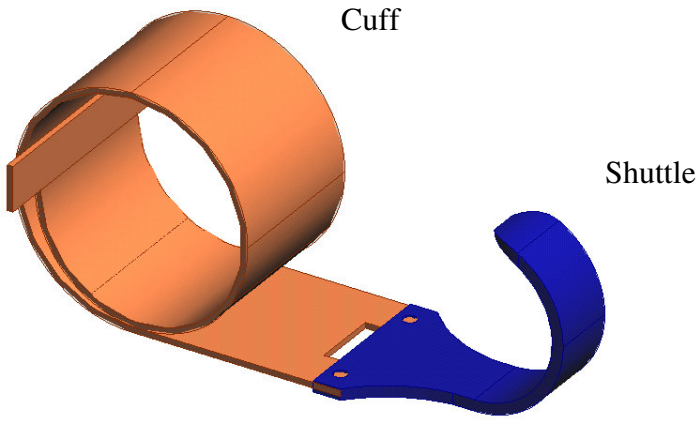

Figure 8. Cuff with concept shuttle attached to end. Shuttle will be used to feed the cuff behind the nerve and cut off once installation is complete.

Selectivity:

The stimulation levels needed to evoke a response during the intra-operative testing sessions were in the range of 2 mA, 200 μsec. These are consistent with those recorded last quarter and higher than had been expected based on previous values of cuff stimulation in animals, which are in the range of 0.5 mA, 10 μsec [Grill 1996; Grill 1998]. It was previously discussed (see QPR9-N01-NS-1-2333) that the injured nerves could be less excitable then healthy nerves. However, this quarter, data was recorded from a paralyzed subject. These nerves were not damaged, but they had not been active for two years. The higher stimulation values could be a property of human nerve compared to animals or it could be due to disuse of the paralyzed nerves. In order to finalize development of an implantable stimulator, it is necessary to establish functional stimulation ranges. Unfortunately, there are many variables in the intraoperative procedures that are uncontrollable, so this data could be atypical. Therefore, the first priority once a subject is permanently implanted with cuff electrodes will be to thoroughly characterize the recruitment properties and the stimulation stability with nerve cuff electrodes.

Stimulation of the upper truck of the brachial plexus (C5/C6) resulted in selective activation of the biceps muscle. There is controversy regarding nerve fascicle organization within a nerve fiber. It is not known whether all the fascicles innervating a certain muscle are

grouped proximally in the nervous system. The fact that stimulation at one point on the upper trunk of the brachial plexus (proximal nervous system) resulted in activation of a single muscle suggests that synergistic motor units may be arranged coherently as high as the trunks of the brachial plexus.

Future Work

Nerve cuff electrodes with percutaneous leads will be implanted in a human subject for one year. Following the testing, the subject will be offered an implanted system to provide hand and arm function. The purpose of the testing is to fully characterize the recruitment and selectivity properties of the cuff electrodes. Recruitment curves will be measured using both pulse width and pulse amplitude modulation. The ability to achieve selective full recruitment of muscle groups innervated by the radial nerve will be evaluated. We will also determine if sufficient force can be obtained from partially denervated muscle and if responses are repeatable and stable.

Goals for the next quarter include:

- Finalize tool design
- Fabricate final tool
- Prepare for percutaneous implantation
    - Specify and fabricate external stimulator
    - Develop testing protocol
    - Prepare design history file for electrode and implant tool

References

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Wireless Data Acquisition Module for Use with a Neuroprosthesis

Contract section: E.1.a.v Sensory feedback of contact and grasp force

Abstract

A general wireless data acquisition module (WDAM) is being developed for use with a neuroprosthesis. The WDAM is intended to be used with sensors such as the shoulder or wrist position transducer, finger-mounted joysticks, or remote on-off switches. Currently these sensors are connected to a controller via cables, which are cosmetically unappealing to the user and often get caught on wheelchairs, causing them to be damaged. Switch-activated transmitters mounted on walkers have been used previously in FES applications [1]. Recent advances in wireless technology have reduced the complexity and size of the wireless circuitry and have

increased the likelihood that a small, low power, reliable wireless link could be assembled from commercially available components.

Methods & Results

In the previous progress report, a prototype circuit for the WDAM was described. This included the transceiver, microcontroller, power regulator and buffer/amplifier components, but not some of the extraneous components (such as LEDs and potentiometers) that were part of a development kit system that utilized too much power. The current requirements for the WDAM were reduced from 25-30 mA for the development kit system to 4-5 mA for the prototype circuit. Efforts in the past quarter were focused on evaluating different software protocols to further reduce the current draw for the prototype circuit.

Three different software protocols were evaluated during this quarter. The protocols were compared based on the power used, the percentage of original packets acknowledged, and the number of times an original packet needed to be re-sent. The results are summarized in Table 2.

Continuous data protocol

The first protocol will be referred to as the "continuous data protocol", and is the protocol that had been used in the previous evaluations. In the continuous data protocol, a WDAM module that is attached to a sensor (the "sensor module") continuously samples data, then forms and transmits data packets. A second WDAM module which has a serial connection to an external controller (the "central module") listens for data packets, determines if they were received properly, then sends a reply packet containing either an acknowledgement or an error code. The sensor module waits for a reply, and then either re-sends the packet (if the reply is not received or has an error) or moves on to the next data packet (if the reply is an acknowledgement). This protocol required an average current of 4 mA, with 12 mA peaks during packet transmission. Original packets were successfully acknowledged up to 94% of the time. However, each packet needed to be re-sent an average of 3 times before it was successfully acknowledged.

Master/slave protocol

The second protocol is a master/slave protocol. In this protocol, the central module (the 'master') requests data from a sensor module (the 'slave') and then waits for a reply. The sensor module listens for a data request. When it detects an appropriate request, it samples data, then forms and transmits a packet, then goes back to listening for other requests. Upon receiving the data packet, the central module determines if it was received properly. If it was not received properly, the data request is sent again. If the data was received properly, or if it was not received properly after four attempts, the central module moves on to the next data request.

One advantage of this protocol is that the sensor module can be put into a low-power sleep mode for short periods of time. This should result in an overall reduction in the power consumption, as long as it is awakened frequently enough to successfully detect the data requests. In trials where the sensor module was put in sleep mode for 20 msec periods, the average current draw was 2.4 mA (1 mA during sleep mode, 4 mA while receiving data, and 6 mA spikes while transmitting). Original packets were successfully acknowledged up to 97% of the time. Sixty-five percent of the original packets needed to be re-sent.

Delta data protocol

The third protocol will be referred to as the "delta data" protocol. In this protocol, the sensor module's microcontroller continuously samples the data while the transceiver is in the low-power sleep mode. If the data value changes by more than a set threshold value, then the microcontroller forms a data packet, wakes the transceiver, and sends the data packet. The central module listens for data packets, determines if they were received properly, then sends a reply packet containing either an acknowledgement or an error code. The sensor module waits for a reply and then either re-sends the packet (if the reply is not received or has an error) or puts the transceiver back into sleep mode and goes back to sampling the data (if the reply is an acknowledgement).

The power requirements for this protocol depend on the selected threshold and the type of input signal that is being sampled. In these trials, the data change threshold for initiating a packet was selected to be 10% of the input range. Two types of input signal were tested. One was a switch input, where the input value changed from the minimum to maximum value when the switch was pressed, and changed back to the minimum value when the switch was released. The other input was a 4-volt peak-to-peak, 1 Hz sine wave signal. In trials with the switch input, the sensor module used 0.9 mA when the transceiver was in sleep mode, and had an average current draw of 2.3 mA when the switch was pressed and released (including 6 mA spikes when the data packets were transmitted). In trials with the sine wave input, the sensor module had an average current draw of 3.3 mA. With both input signals, original packets were successfully acknowledged up to 93% of the time. The number of original packets that needed to be re-sent was not measured in this protocol.

Table 2. Summary of Results for Different Software Protocols

Software Protocol	Packet trigger	Avg. Current Draw	% Acknowledged	% Re-sent
Continuous Data	Continuous	4.0 mA	94 %	100 %
Master/Slave	Master request	2.4 mA	97 %	65 %
Delta Data: *Switch Input*	Data change	0.9 – 2.3 mA	93 %	Not tested
Delta Data: *Sine Wave Input*	Data change	3.3 mA	93 %	Not tested

Next Quarter

In the next quarter, battery longevity tests will be performed. Since the longevity of a battery is dependent on several variables, it is difficult to determine from a manufacturer's specifications how a battery will perform under specific conditions. Three different types of primary (replaceable) coin cell batteries (lithium, silver oxide, and zinc air) have been purchased. Each of these battery types will be used to power a sensor module. The length of time that the sensor module is able to successfully transmit data will be recorded for each battery type.

Once the optimal battery is identified, a printed circuit board version of the WDAM will be fabricated. It is likely that this will increase the acknowledgement rate and decrease the re-transmission rate for the WDAM, since it is likely that many of the transmission errors are due to noise that is picked up from the soldered wires that are used in the prototype circuit.

Faster transceiver modules that were received this quarter will also be evaluated in the next quarter. The fastest transceiver module has a data rate that is 50 times faster than the one currently in use. Although we do not anticipate needing data transmission rates that are that high, the quicker rates will allow the transceiver to spend more time in sleep mode, and therefore will reduce the power requirement further.

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